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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,932	10/15/2001	Daniel G. Chain	CHAIN=1C	2674

7590 12/20/2002

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EXAMINER	
CROUCH, DEBORAH	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 12/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/975,932	Applicant(s) CHAIN, DANIEL G.
	Examiner Deborah Crouch, Ph.D.	Art Unit 1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *28-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicant's election with traverse of group I, claims 1-27 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the subject matter of group II can be searched with the elected subject matter and not be burdensome to the examiner. This is not found persuasive because the restriction/election requirement mailed May 21, 2002 in paper no. 5 indicates that inventions I and II are in separate classifications. Therefore, the examiner would need to perform non-coextensive searches. Invention I is to methods involving administering a DNA sequence encoding an antibody. Invention II is to methods involving administering an antibody. These methods are materially different and separate because of the protocols requirement to implement the methods. The protocol for invention I is not used in the protocol for invention II, and vice-versa.

The requirement is still deemed proper and is therefore made FINAL.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 1-27 are drawn to methods of preventing or inhibiting progression of Alzheimer's Disease comprising administering a recombinant DNA molecule comprising a gene encoding a recombinant antibody molecule end-specific for the N-terminus or the C-terminus of an amyloid-β peptide operably linked to a promoter to prevent the accumulation of amyloid β peptide and the aggregation of peptides which form amyloid deposits in the

brain, claims to the recombinant DNA molecule, and pharmaceutical compositions comprising the recombinant DNA molecule.

The claims lack enablement because the art teaches that the administration of antibodies to human AD patients resulted in significant complications such that clinical trials had to be suspended. After four months of treatment, where a vaccine comprising Aβ was administered to mildly to moderately afflicted AD patients in a phase II trial, the trial was suspended because some of the patients showed signs of central nervous system inflammation, and two patients had strokes (Steinberg, page 1, parag. 3 and 4). Further, those individuals affected negatively by the peptide vaccine, exhibited a worsening of the Alzheimer's symptoms such as confusion and inability to perform basic living tasks (Steinberg, page 2, parag. 1).

The specific examples in the specification disclose methods of preparing peptides for antibody production, production of antibody to the C-terminus and the N-terminus, cloning the genes for the C-terminus and N-terminus antibodies into vectors, for example AAV, and a prophetic example of mating an TGScFvA mouse with an TG2576 mouse. However, none of the specific examples to provide guidance in overcoming the deleterious effect of the expression of antibody to β-amyloid protein or a fragment of the β-amyloid protein. Without such guidance the ordinary artisan would need to engage in an undue amount of experimentation without a predictable degree of success to implement the invention as claimed.

Furthermore, the instant invention, as claimed, falls under the "germ of an idea" concept defined by the CAFC. The court has stated that "patent protection is granted in return for an enabling disclosure, not for vague intimations of general ideas that may or may be workable". The court continues to say that "tossing out the mere germ of an idea

does not constitute an enabling disclosure" and that "the specification, not knowledge in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement". (See Genentech inc v. Novo Nordisk A/S 42 USPQ2d 1001, at 1005). The claimed method constitutes such a "germ of an idea".

The claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 703-308-1126. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Deborah Crouch

Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

dc
December 18, 2002